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Hyper-thermic Nd:YAG Laser Lipolysis Assisted by Dry Molecular Skin Cooling

Jure Kosir[1], Tomaz Cvetko[1], Matjaz Lukac[1,2,3]
[1]Fotona d.o.o., Stegne 7, Ljubljana, Slovenia
[2]Institut Josef Stefan, Light and Matter Dept., Jamova 39, Ljubljana, Slovenia
[3]University of Ljubljana, Faculty of Mathematics and Physics, Jadranska 19, Ljubljana, Slovenia

ABSTRACT

The hyper-thermic laser lipolysis (HTLL) procedure consists of irradiating the skin with deeply penetrating Nd:YAG (1064 nm) laser light in order to heat the adipocytes to hyper-thermic temperatures within the deeply lying fat tissue layer, while cooling the superficial skin layers to prevent pain and tissue damage.

In particular, the TightSculpting® HTLL procedure has attracted significant attention due to its protocols developed for non-contact delivery of laser energy over large body areas using a laser scanner and a forced cold air skin-cooling (CAC) device.

Recently, a novel skin-cooling technology, CoolMist™ has been introduced that is based on dry molecular cooling (DMC™) of the skin surface. In this study, the cooling characteristics of DMC™ and CAC are compared, with a goal to define protocols for DMC-assisted HTLL by adapting and optimizing the TightSculpting HTLL protocols originally developed for CAC cooling.

Key words: lipolysis, apoptosis, dry molecular cooling, cold air cooling, Nd:YAG laser, thermal imaging.

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I. INTRODUCTION

The transcutaneous delivery of laser energy to the adipose tissue has in recent years become popular since it offers a less invasive alternative to surgical laser lipolysis [1-3]. This hyper-thermic laser lipolysis (HTLL) procedure consists of irradiating the skin with deeply penetrating Nd:YAG (1064 nm) laser light in order to heat the adipocytes to hyper-thermic temperatures in the range of 43–47 °C for a prolonged time, which has been found to lead to programmed adipocyte cell death [4-9].

The goal is to heat the adipocytes within the deeply lying fat tissue layer while keeping the superficial skin layers at temperatures below the pain and damage threshold. Since the laser light must pass through the epidermis before reaching the deeper lying fat tissue, and the Nd:YAG laser light is strongly absorbed in both the epidermis and dermis, this means that appropriate cooling of the skin surface is as important for safe and effective HTLL as the laser irradiation itself. Therefore, an HTLL protocol must include not only laser parameters but also the method and parameters for accompanying skin cooling.

Defining an appropriate combination of laser and cooling parameters represents somewhat of a challenge since the information on the achieved temperatures at the location of the adipocytes is not readily available [10,11].

During recent years, the two-step TightSculpting® procedure has attracted significant attention [16-23], with one of the steps in the HTLL procedure consisting of PIANO® mode Nd:YAG laser [16]. The TightSculpting protocol consists of a non-contact delivery of laser energy over large body areas using a laser scanner and a forced cold air skin-cooling device.

In a very detailed study by Milanic et al. [1], a numerical model of the TightSculpting lipolysis was developed and applied to model human skin temperatures during HTLL. It was shown that the temperature and adipocyte damage distribution within deeper tissue layers can be estimated from the measured temporal evolution of the skin surface temperature, and can be controlled by stopping the laser irradiation at pre-defined skin surface threshold temperatures. Based on the results of this study, a set of TightSculpting HTLL protocols was developed, with the assumption that the skin cooling during HTLL is carried out by a forced cold-air cooling (CAC) method [16]. Using these protocols that were defined for different skin types, the CAC-assisted TightSculpting HTLL procedures have been safely and effectively performed by clinicians for many years [16-23].

Recently, a novel skin-cooling technology, CoolMist™ [12-15] has been introduced, which improves upon the CAC method. The CoolMist™

technology is based on dry molecular cooling (DMC™) of the skin surface, overcoming some of the disadvantages of the standard cooling methods by delivering a digitally controlled very fine water mist to the laser-treated skin surface.

In this study, the cooling characteristics of DMC and CAC were measured and compared, with a goal to define protocols for DMC-assisted HTLL by adapting and optimizing the TightSculpting HTLL protocols originally developed for CAC cooling. The newly developed protocol was then tested and evaluated by performing a DMC-assisted HTLL procedure [16-20].

II. MATERIALS AND METHODS

a) CAC-assisted HTLL protocols

The TightSculpting HTLL protocols [1, 16], were developed specifically for a Dynamis 1,064 nm Nd:YAG laser device equipped with a scanning L-Runner handpiece (both manufactured by Fotona, d.o.o., Ljubljana), in combination with a forced air chilling device Cryo 6 (manufactured by Zimmer, G.m.b.H, Germany). The cold air flow of the Zimmer device is adjustable through FC = 1-9 different levels.

During HTLL the skin is homogenously irradiated over an area S of up to approx. 8 x 8 cm² using the L-Runner laser scanner. The complete area S is irradiated by repeated quick scanning of the area with individual laser spots of 11 mm diameter. For example, for the maximal scan size of the L-Runner scanner of 8 x 8 cm², each scan requires 70 pulses (pulse duration of 0.6 ms) to cover the whole area within 2.8 seconds. Since the scan time is much shorter than the tissue cooling time, which is on the order of several minutes, this ensures that during the repeated scanning (lasting for an irradiation time of several minutes), the area is heated approximately homogeneously with an average irradiance G (in W/cm²) (see Fig. 1).

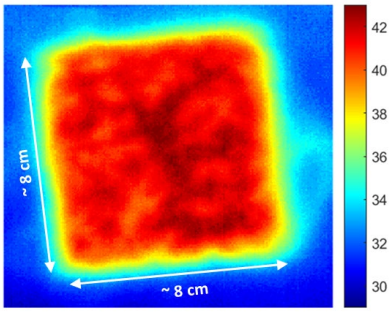

Fig. 1: Exemplary thermographic image of the irradiated skin after 3.1 min of irradiation by G = 0.64 W/cm² Nd:YAG laser and natural convection cooling.

An example of the temporal evolution of the skin temperature during a scanned irradiation with G = 1.2 W/cm² and FC=1 cooling for t = 2 minutes is shown in Fig. 2.

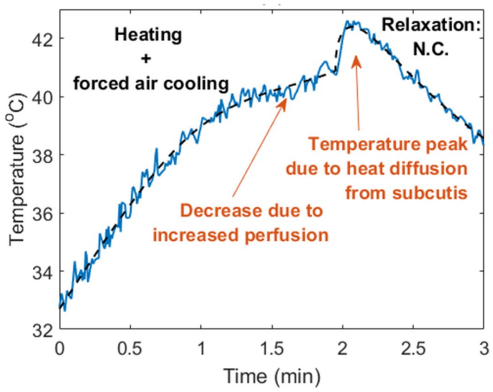

Fig. 2: Thermal signal (blue line) recorded on abdominal skin of a patient, and corresponding fit (dashed line). A "plateau" due to blood perfusion and relaxation temperature peak are evident. Irradiance G = 1.2 W/cm² and cold air cooling with FC=1, were used. Irradiation duration 2 min.

As can be seen from Fig. 2, after the irradiation and forced cold air cooling have been stopped, the skin surface temperature started to increase due to the heat being thermally conducted to the surface away from the temperature peak located deeper within the tissue (see Fig. 3).

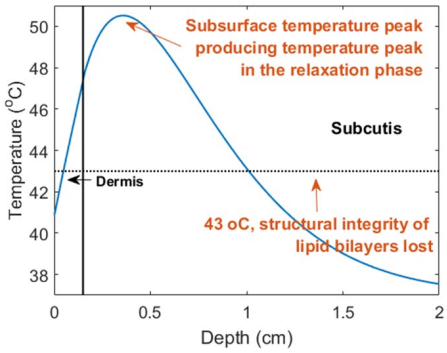

Fig. 3: Temperature depth profile at the end of the 2 minutes long irradiation simultaneously with CAC. A prominent temperature peak is present in the subcutis while the epidermis and dermis are cooled down and thus protected against overheating.

The TightSculpting HTLL protocol consists of a cycled irradiation procedure where the treated areas are divided into four adjacent skin areas, which are sequentially heated in a cyclical manner as depicted in Figure 4, with G = 1.2 W/cm² under CAC conditions. Each skin area S is irradiated until the skin temperature T_s reaches a prescribed surface threshold temperature (T_{st}), after which the irradiation is moved to the next area within the cycle. The T_{st} value is chosen for different skin types, based on a numerical model and thermal camera measurements [1]. The four-area cycle is repeated N times and after the last irradiation, the

skin temperature is allowed to relax to the initial temperature by means of natural convection cooling.

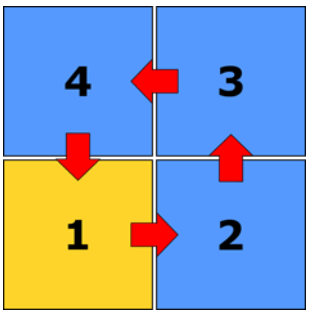

Fig. 4: Cyclical irradiation protocol. Four adjacent skin areas S are sequentially heated for N consecutive cycles.

The HTLL protocols as developed for the Fotona Dynamis Nd:YAG laser, equipped with the L-Runner scanner and Zimmer Cryo 6 cold-air cooling device are presented in Table 1 below. This protocol is also known as PIANO sculpting [16], and is often performed in combination with the Fotona SMOOTH® tightening procedure using the Er:YAG (2940 nm) laser [21]. It is the combined treatment that is known as the TightSculpting® procedure [16, 18, 21-23].

Table 1: PIANO sculpting. Recommended cycled HTTL protocols with G = 1.2 W/cm², for different cold air-cooling (CAC) levels and skin types.

	Cold Air Cooling (CAC)	Threshold temperature T_{st} (°C)	No. cycles N
PALE CAUCASIAN	FC 2	38	4-5
	FC 4	35	4-5
	FC 7	32	4
TANNED CAUCASIAN	FC 2	38.5	4-5
	FC 4	36.	4-5
	FC 7	33	4
ASIAN	FC 7	34	4
	FC 9	32	4
AFRICAN	FC 9	33	4

a) Dry Molecular Cooling (DMC)

The CoolMist™ cooling technology generates an atomized liquid spray for the treatment area, wherein the atomized pulsed liquid spray is based on a digitally controlled mixture of liquid and gas. The pulsed application of the spray on the tissue has the advantage that in between two subsequent pulses the evaporation of the droplets leads to a drying of the tissue so that the formation of a water layer on the skin surface is avoided. Further, the CoolMist™ nozzle is operated in such a way as to achieve a fine "micro-pulsed" liquid spray with optimal liquid content, droplet size and velocity, which together enable "dry" molecular cooling (DMC™) based on a quick evaporation of the molecular droplets [13].

The CoolMist™ skin cooling technology has been integrated into the latest Fotona laser systems, such as AvalancheLase® and Nx Dynamis SP. The CoolMist assembly contains a microprocessor-controlled system for precise DMC spray adjustment for the L-Runner scanning handpiece and it's variants: LX-Runner for AvalancheLase®, and Nx-Runner for Nx Dynamis (see Fig. 5). The DMC spray control allows the user to adjust the spray to different water (W = 1-9) and air (A = 1-5) spray level combinations. A detachable cooling water reservoir enables the user to easily re-fill the reservoir with the cooling liquid.

The handpiece scanning is equipped with a non-contact temperature sensor MatrixView™ having an array of thermopile detectors as sensors and infra-red optics for imaging the skin surface. The infra-red image of skin on the thermopile detector array is analyzed, processed, and sent to the host laser system's graphical user interface (GUI) to display the temperature of the treated skin. The handpiece also incorporates a multicolor LED diode for a quick visual indication of when, for example, the skin's temperature reaches the threshold temperature T_{st}.

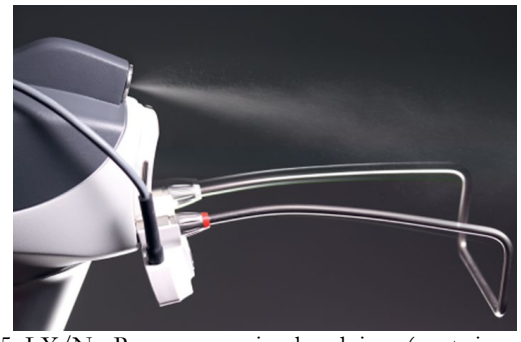

Fig. 5: LX/Nx-Runner scanning handpiece (spot sizes 9 and 11 mm; scan area up to 8 x 8 cm²) with DMC™ spray emanating from the CoolMist™ nozzle.

b) Skin temperature monitoring

The temporal evolution of the skin surface temperature T_S, before, during and following laser irradiation in combination with CAC or DMC skin cooling, was measured with a thermal camera (ThermaCAM P45, manufactured by FLIR Systems, USA). The camera was fixed in position above the patient's skin surface and focused on the treated skin site (Fig. 6).

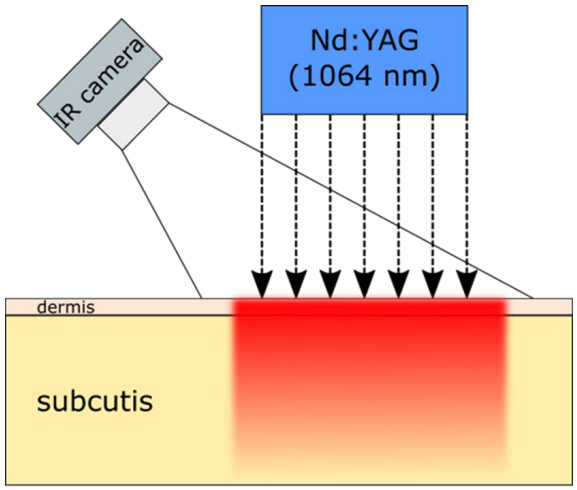

Fig. 6: Experimental set-up.

In addition to monitoring the temporal evolution of the skin surface temperature T_s, a recently published temperature peak estimation method [10,11], was used to also obtain the depth temperature profile deeper within the tissue. The method is based on the recording of the surface temperature evolution following a laser treatment, coupled with a thermal-diffusion-based model and a time-dependent data matching algorithm. The temperature depth profile estimation method relies on a time-dependent surface temperature field (T_s(t)), that is measured following the clinical procedure when the laser and cooling system are turned off. Following the treatment, the temperature T_s changes with a rate that mainly depends on the starting temperature distribution (internal gradient), environmental conditions, and thermal properties of the tissue. Due to the surface cooling, the temperature peak (T_{max}) is not located at the surface but undergoes a shift below the tissue surface (z_{max}). As this internally deposited heat starts to diffuse back to the now un-cooled surface, this is typically observed as a development of a superficial temperature peak on the skin surface (see Fig. 1) that with time slowly relaxes under natural convection back to the initial temperature. Using the time-dependent data matching algorithm, the final temperature depth profile achieved by the end of a treatment can be calculated from the measured temporal development of the skin surface temperature following the treatment.

III. RESULTS

a) Cooling rate of CAC and DMC in the absence of laser radiation

Figure 7 shows the temporal evolution of the reduction of the skin temperature $\Delta T_S = T_S - T_0$ in the absence of laser radiation during skin cooling with either DMC (Fig. 7a) or CAC (Fig. 7b).

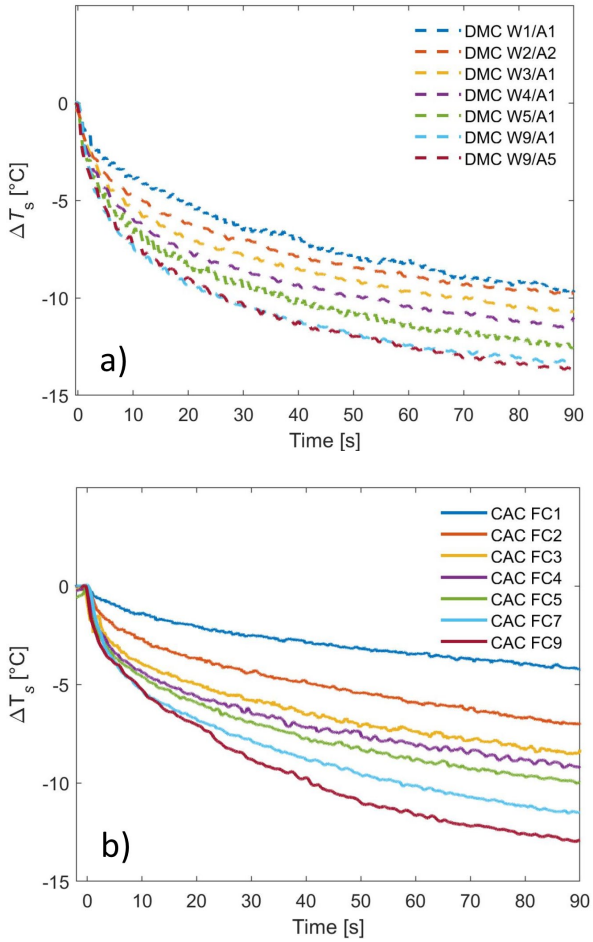

Fig. 7: Measured temporal evolution of the reduction of the skin temperature $\Delta T_S = T_S - T_0$ in the absence of laser radiation during skin cooling with either a) DMC or b) CAC (b).

A comparison shows that the cooling rates of DMC are higher than that of CAC. However, an approximate matching correspondence between certain DMC and CAC settings can be found for the initial cooling rates (See Fig. 8). An approximate correspondence table for all CAC settings is depicted Table 2.

Table 2: Experimentally obtained correspondence of the CAC and DMC settings that result in substantially equivalent skin cooling rates.

CAC setting	DMC setting
FC4	W1/A1
FC5	W2/A1
FC6	W3/A1
FC7	W4/A1
FC8	W5/A2
FC9	W6/A5

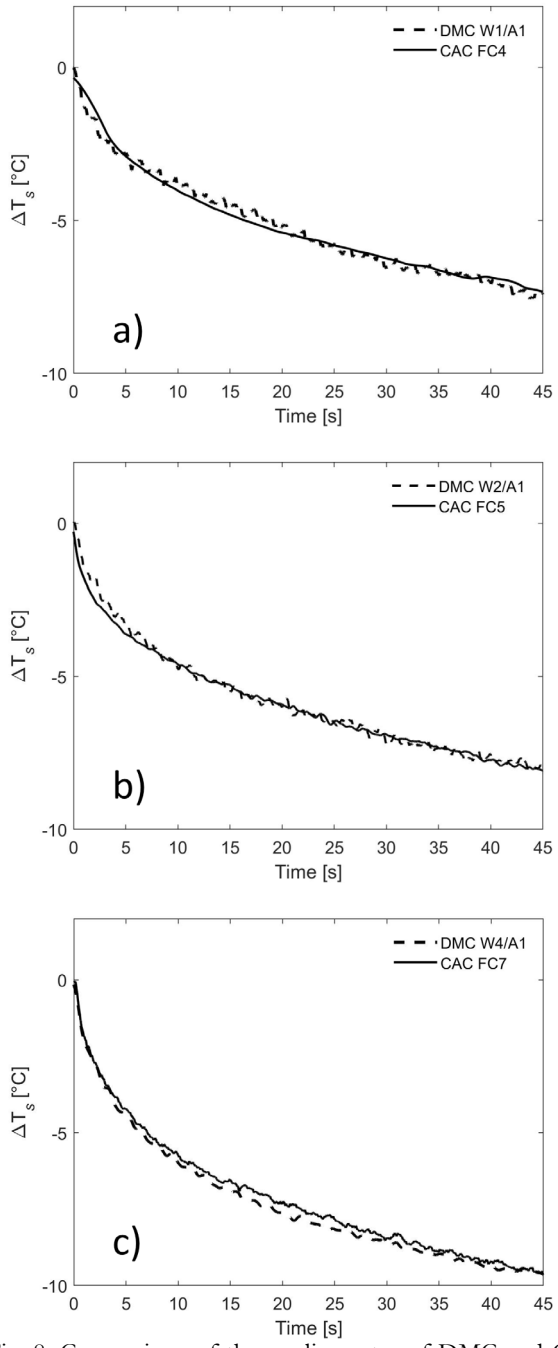

Fig. 8: Comparison of the cooling rates of DMC and CAC. The initial cooling characteristics of DMC W1/A1, DMC W2/A1 and DMC A4/A1 are approximately the same as the initial cooling characteristics of CAC FC4, CAC FC5 and CAC FC7, correspondingly.

b) Skin surface temperature evolution during laser irradiation in combination with CAC or DMC cooling

Figure 9 shows the skin surface temperature evolutions during and following skin irradiation with the same irradiance (G) for 125 s, under simultaneous cooling with either CAC FC4 or DMC W1/A1.

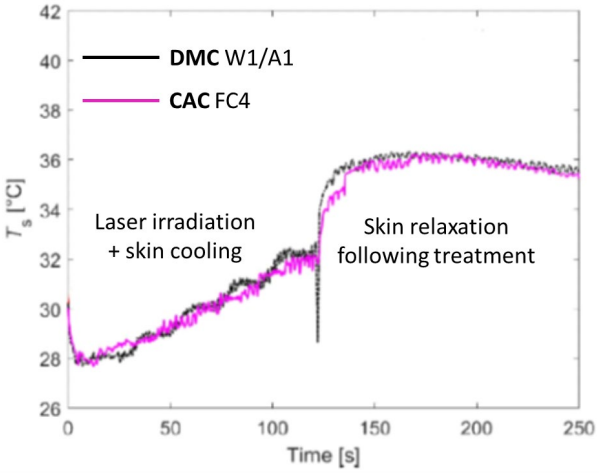

Fig. 9: Comparison of the skin surface temperature evolutions during and following skin irradiation with the same irradiance for 125 s, under simultaneous cooling with either DMC W1/A1 or CAC FC4.

As expected from the measured cooling rates (Fig. 6) and Table 2, the temporal evolutions of the skin surface temperatures substantially coincide when cooling with CAC FC4 or DMC W1/A1 is used.

c) DMC-assisted HTLL

Based on the previously published HTTL protocols for CAC cooling [1, 16], and on the comparison of thermal camera measurements obtained with either CAC or DMC, the following protocols, as shown in Table 3, were developed for DMC-assisted HTLL.

Table 3: PIANO sculpting. Recommended cycled HTTL protocols with G = 1.2 W/cm², for different dry molecular cooling (DMC) levels and skin types.

	Dry Molecular Cooling (DMC)	Threshold temperature T_{st} (°C)	No. cycles N	Depth of apoptosis (cm)
PALE CAUCASIAN	W1/A1	35	4-5	0.4-2.1
	W4/A2	32	4	0.5-2.2
TANNED CAUCASIAN	W1/A1	36	4-5	0.4-2.1
	W4/A2	33	4	0.5-2.2
ASIAN	W4/A2	34	4	0.5-2.2
	W6/A5	31	4	0.5-2.5
AFRICAN	W6/A5	33	4	0.5-2.5

Using the recommended protocols (Table 3) a 4-cycle DMC-assisted HTLL treatment was performed on one of the authors (skin type II). The skin surface temperature evolution within one of the four quadrants during and following the treatment is shown in Fig. 10.

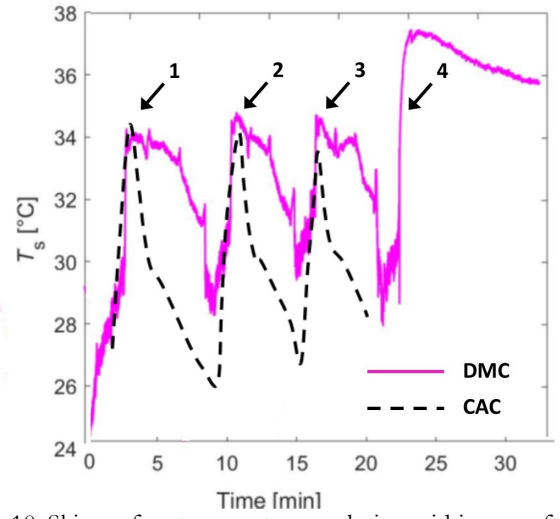

Fig. 10: Skin surface temperature evolution within one of the four quadrants during and following the DMC-assisted HTLL treatment using G = 1.2 W/cm², DMC W1/A1, and T_{st} = 34°C (purple line). The arrows indicate the four cycles of laser irradiation. For comparison, an example of the previously published temperature behavior during a CAC-assisted HTLL [1], is also shown (doted black line).

Finally, Fig. 11 shows the estimated temperature depth profile as obtained by matching the time-dependent algorithm to the measured skin surface temperature relaxation following the treatment.

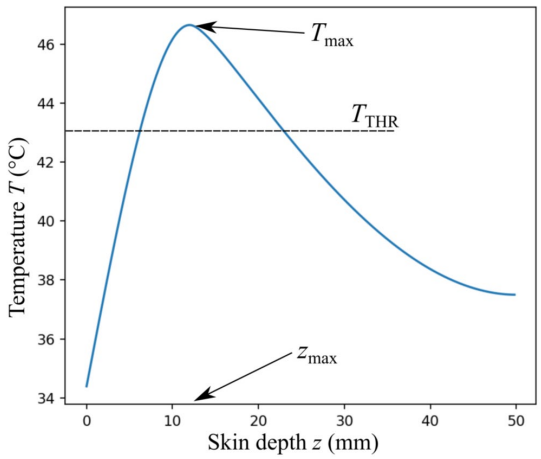

Fig. 11: The estimated temperature depth profile following the DMC-assisted HTLL cycling shown in Fig. 9. The dashed line represents the temperature threshold for apoptosis T_{thr}= 43°C.

As can be seen from Fig. 11, by the end of the DMC-assisted HTLL, the tissue that was heated to temperatures above the threshold for apoptosis is located within the skin depth of z = 4 - 21 mm.

IV. DISCUSSION

The transcutaneous hyperthermic Nd:YAG laser lipolysis known also as the PIANO sculpting treatment [16], when performed according to the TightSculpting® protocol [1, 16, 18, 21-23], has proven to be a safe, minimally invasive, and effective solution for body contouring.

Until recently, the body sculpting step of TightSculpting has been performed solely using cold air cooling (CAC) during the procedure. The CAC method represents an excellent solution for TightSculpting since it allows non-contact treatments over of large body areas using the Runner™ laser scanning technology.

The recently introduced CoolMist™ technology provides another solution for performing TightSculpting on large body areas in a non-contact manner. In this study it has been demonstrated that the protocols originally developed for TightSculpting using the CAC cooling method can be directly adopted for the more effective DMC cooling approach.

An important advantage of implementing DMC into the TightSculpting protocols can be concluded from Fig. 10. In this figure, the skin surface temperature evolution during the four cycles of the DMC-assisted HTLL treatment is depicted together with the published temperature evolution during CAC-assisted HTML. The skin temperatures resulting from the CAC-assisted protocol display sharp temperature peaks during each cycle, indicating that substantial cold-air cooling that is less spatially localized than DMC is present also during the off periods, i.e., when the laser is irradiating other quadrants. On the other hand, the temperature of the DMC cooled quadrants remains high also during the off periods. This is an important difference since the level of the adipocytes damage grows linearly with the duration of the exposure to above damage threshold temperatures. The DMC-assisted HTLL is therefore expected to be more effective in inducing apoptosis and promoting fat reduction.

V. CONCLUSIONS

In conclusion, the TightSculpting® HTLL protocols that were originally developed for cold air cooling have been upgraded to incorporate the recently introduced novel skin cooling technology (CoolMist™) based on dry molecular cooling (DMC™) of laser-irradiated skin. Compared to CAC, the DMC-assisted HTLL is more comfortable for the patient, and is expected to be more effective in inducing apoptosis and promoting fat reduction. Additionally, the CoolMist™ is integrated directly into the laser device and does not require an additional external air chilling device.

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